

ABSTRACT

In human disease states caused by bacteria, whether the bacteria are of the Gram stain-positive or Gram-stain negative type, any carbohydrate antigens possessed by the bacteria tend to manifest themselves in the bodily fluids of the infected patient early in the onset of the disease and to persist there at least up to that patient's cure. According to this application which is a continuation-in-part of and incorporates by reference each of the copending, commonly assigned applications Serial No. 09/139,720 filed August 25, 1998 and 09/399,710 filed September 16, 1999 as a continuation of Serial No. 09/156,486 filed September 18, 1998 and now abandoned, highly reliable immunoassays for these various carbohydrate antigens in human bodily fluids are based upon detecting these antigens with purified polyvalent antibodies to the bacteria which are appropriately tagged as needed.

More specifically, polyvalent antibodies to a bacterial carbohydrate antigen are purified according to a process which begins with isolating carbohydrate antigen from the bacteria in highly purified form containing no more than 10% protein, coupling this purified antigen to an affinity column and purifying the polyclonal antibodies to the bacteria by chromatographing them over the affinity column to which the purified antigen is coupled. Particularly sensitive and specific assays for the unpurified carbohydrate antigen in human bodily fluids are immunochromatographic ("ICT") assays wherein the purified antibodies are coupled to a tag such as colloidal gold and another increment of untagged purified antibodies is immovably striped as the capture line on an ICT test strip. The sample of bodily fluid is then supplied to the sample receiving area of the strip where it picks up a mobile deposit of tagged antibody

with which it flows along the strip to the capture line. During flow, carbohydrate antigens, if contained in the sample, form conjugates with the tagged antibodies. When the flow reaches the capture line, these conjugates form "sandwiches" with the fixed antibodies on that line and a definite color appears along the line. These assays can be completed in 15-20 minutes and are highly useful in situations where rapid diagnosis of disease, based on assay result plus observed clinical symptoms of the patient, is important.